University Animal Care Committee Standard Operating Procedure		
Document No: 14.1	**Subject:** Management of Controlled Substances	
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Location: Queen's University

Responsibility: Principal Investigators, Research Staff, Veterinary Staff

Purpose: The purpose of this Standard Operating Procedure (SOP) is to describe general laboratory-based responsibilities regarding the management of controlled drug use.

1. **Introduction and Definitions:** Controlled substances are regulated through Health Canada and the Controlled Drugs and Substances Act (S.C. 1996, c.19). Federal regulations must be followed as well as compliance with Queen's University Environmental Health and Safety guidelines.

Abbreviations: Animal Care Services **ACS**, Principal Investigator **PI,** subcutaneous **SC**, intravenous **IV**, intraperitoneal **IP,** intramuscular **IM**, per os **PO,** per rectum **PR**

2. **Materials:**
   - Valid exemption permit http://www.hc-sc.gc.ca/hc-ps/substancontrol/exemptions/applic-scien-eng.php
   - Acceptable storage unit and padlock
   - Separate lock box with key for control drugs to be kept in which is then stored in the storage unit
   - Alcohol swabs
   - Bleach
   - Glass beaker
   - Absorbent pads (or kitty litter)
   - Sharps container
   - Chemical waste container (from Queen's Environmental Health and Safety)
   - Log book to keep track of all control drugs

3. **Procedures:**
   - **Procurement:**
     - The procurement and the use of controlled substances are under legislation and must follow all regulations.
     - Each and every PI with a controlled substance listed on their AUP must have a valid exemption in place (for each and every compound)

OR

- The controlled substance must be administered by a technician under the direct supervision of the University Veterinarian, with the controlled substance purchased on the University Veterinarian's license.
- Individual PIs are responsible for submitting a drug exemption request to Health Canada; and for the acquisition, storing and disposal of controlled substances.
- The application approval process for an exemption permit can take 6+ weeks; the approval process must be taken into consideration in advance of study commencement.
- Sharing of controlled substances is absolutely forbidden.
- Animal Care Services cannot dispense controlled substances.
- A checkbox has been added to CIHR grant applications for the indication of whether controlled substances will be required. CIHR will then contact Health Canada to ensure that a valid exemption is on file.

- **Storage:**

  - It is the lab's responsibility to know the security level of the substances in use and abide by all storage requirements.
  - Storage must meet the requirements of the "Directive on Physical Security Requirements for Controlled Substances", available on the Health Canada website http://www.hc-sc.gc.ca/hc-ps/substancontrol/substan/securit-eng.php and is dependent upon the security level/classification assigned to the drug.

- **Use:**
  *** See log book examples appended to this SOP ***

  - For all controlled substances, log books must be maintained, a book monitoring unopened and opened drugs. This will include the unopened inventory, volumes withdrawn directly from the source, but must also record the volume injected directly into the animal (the volume recorded on the back of the cage card).
  - The use of expired drugs is forbidden.
  - Each and every injection requires a new sterile syringe and needle.
  - Bottles in use should have the rubber stopper wiped with an alcohol swab between uses to maintain sterility.

- The UACC requires that all secondary substance containers (aliquots) are labelled appropriately. If secondary containers are used, they must be glass (red top vacutainers are ideal for this purpose). The containers must be labelled with the name of the drug, the concentration, lot number, and the expiration date from the initial source(s). Drugs should be stored as per manufacturers specifications.
- Drug cocktails (combination of drugs and/or diluent) should be the minimum of quantity required for each individual procedure. Drug cocktails should not be used past two weeks from the date of being combined.

- **Disposal:**

  - Once controlled substances reach their expiry date or are no longer in use, they must be disposed of appropriately.
  - The destruction of controlled substances must be witnessed by a member of the lab.
  - Immediately following the destruction, the witness and Principal Investigator are required to sign and print their names in the controlled substance log book, corroborating the substance has been altered or denatured to such an extent that its consumption has been rendered impossible or improbable.
  - An EH&S form must be filled out (attached), a copy maintained in the lab, and a copy forwarded to EH&S. Waste Disposal | Office of Risk and Safety Services (queensu.ca)
  - Withdraw the remainder of the drug from the bottle using a needle and syringe. The volume should reflect the "Balance in Bottle" recorded in your controlled substances log book.
  - Denature the compound (that which you have drained from the bottle into the syringe).
    This is achieved by adding the drug into bleach – transferring from the syringe into ~2.5 cm of bleach in a glass beaker (ideally within a hood).
  - Transfer this waste (bleach and denatured drug) into a chemical waste/solvent waste container. These are available through Waste Disposal | Office of Risk and Safety Services (queensu.ca) (EH&S).
  - Deface the original empty bottle and any secondary containers (remove label, scratch out or Sharpie over the name). Dispose of this bottle in your lab glass disposal or an approved sharps container.
  - When the lab calls for chemical waste pick up (full containers, or on-schedule), only the substance used to denature the drug needs to be identified, i.e. the bleach.

- Disposal of the substance onto absorbent pads or kitty litter is also acceptable, (the pad/litter thereafter treated as biological waste), however EH&S's preferred method is the denaturing of the compound in bleach. Steps other than the expulsion of the drug onto the pad/litter remain the same.

References:

SOP Revision History:

Date	New Version
April 26, 2018	Triennial Review
March 29, 2019	Review and update
March 10, 2022	Triennial Review
January 23, 2023	Updated format, ACS can dispense controlled drugs updated